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ORLANDO, AMBER ROSE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,402

Applicant(s)

BURFOOT, DEAN

Examiner

AMBER ORLANDO

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the correspondence filed 04/20/2010.

Claims 1, 12 and 14 have been amended.

Claims 22 and 23 are new.

Claims 3 and 13 are cancelled.

Claims 1, 2, 4-12 and 14-23 are rejected.

Claims 1, 2, 4-12 and 14-23 have been examined and are pending.

The applicant appears to be attempting to invoke 35 U.S.C. 112 6th paragraph in claims 1, 12 and 14 using the phrase "means for" and being modified by functional language.

The applicant fails to invoke 35 U.S.C. 112 6th paragraph because the phrase "means for" is modified by sufficient structure for achieving the specified function (e.g. said means comprising an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and boundary wall form a tray...")

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/20/2010 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where within the original disclosure does the applicant disclose "the upstanding boundary wall does not have an inwardly projecting lip".

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1, 2, 4-12, and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howorth US 4,531,956 in view of Marsh et al. US 3,629,999.
4. For claim 1, the Howorth reference discloses a sterile air trolley comprising a mobile casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), and means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface, said means comprising, the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), and the filtered air is emitted inwardly over the work surface from the side walls in use (column 2, lines 24-28, "create an air barrier over the well" shows the filter emitting air inwardly also see figure 1 object 36). The reference does not disclose an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface, and the boundary wall comprising first an second pairs of opposing straight, parallel side walls. Merely changing the shape of the filter (from a circle, to the boundary wall comprising first an second pairs of opposing straight, parallel side walls) does not render

patentability. The specification contains no disclosure of either the critical nature of this requirement or any unexpected results arising therefrom, and as such this requirement would be arbitrary and therefore obvious. Applicant must show that this requirement is critical. In re Woodruff, 16 USPQ 2d 1934.

5. The Marsh et al. reference discloses an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall form a tray, the boundary wall extending fully around the perimeter of the work surface, and the walls emitting filtered air on all sides (figure 1, objects 36 and 28). The reference does not explicitly state the boundary wall being hollow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall being hollow since the examiner takes Official Notice of the equivalence of the wall of Marsh (objects 36 and 28) and the applicants hollow wall for their use in the air outlet art and the selection of any of these known equivalents to provide an outlet for filtered air would be within the level of ordinary skill in the art.

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall forming a tray, the boundary wall extending fully around the perimeter of the work surface and the walls emitting filtered air on all sides (Marsh et al. figure 4, figure 1, objects 36 and 28) because this allows for the objects to be sterilized to be securely within the apparatus and the all over flow of sterilized air.

7. For claim 2, the Howorth reference discloses the need for all over flow of sterilized air from the work surface, and forming a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume (figure 2 objects 22 a and 22b). The reference does not disclose the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall.

8. The Marsh et al. reference discloses the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall (column 2, lines 24-27).

9. It would be obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the sterile/filtered air being directed across the work surface from all directions inwardly of the boundary wall and forming a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall (Marsh et al. column 2, lines 24-27) because this allows for the objects to be sterilized to be securely within the apparatus and the all over flow of sterilized air.

10. For claim 4, the Howorth reference discloses filtered air being emitted from the work tray on all sides (figure 2 objects 22 a and b). The reference does not disclose the all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle.

11. The Marsh et al. reference discloses the boundary wall defines all sides of the tray and the filtered air being emitted inwardly over the work surface from all sides (figure 4 object 36). The reference does not disclose the boundary wall in the shape of a rectangle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the boundary wall in the shape of a rectangle since the examiner takes Official Notice of the equivalence of the tray/boundary wall in the shape of a circle of Marsh (objects 36 and 28) and the applicants tray/boundary wall in the shape of a rectangle for their use in the air tray and outlet art and the selection of any of these known equivalents to provide an tray for surgical items and an outlet for filtered air would be within the level of ordinary skill in the art.

12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include all sides being in the shape of a tray that is rectangular, the boundary wall defining the four sides of the rectangle, and the filtered air being emitted inwardly over the work surface from all sides (Marsh et al. figure 4 object 36) because this allows for the objects to be sterilized to be securely within the working tray.

13. For claim 5, the Howorth reference discloses the trolley casing is in a modular form having a base unit housing the impeller and an upper unit comprising the work surface (figures 1 objects 11 and 12, and figure 2 object 17). The reference does not disclose the work surface being tray-shaped with a boundary wall, and the upper unit being readily demountable from and re-mountable to the base unit.

14. The Marsh et al. reference discloses the work surface being tray-shaped with a boundary wall (figure 1 objects 36 and 28).

15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface being tray-shaped with a boundary wall (Marsh et al. figure 1 objects 36 and 28) because this allows for the objects to be securely within the working tray.

16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the upper unit being readily demountable from and re-mountable to the base unit, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicman*, 168 USPQ 177, 179.

17. For claim 6, the Howorth reference does not disclose sterilized surgical instruments are set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface.

18. The Marsh et al. reference discloses a tray that has the ability to have sterilized surgical instruments on the top of the surface, and to mount foil or a lid on the top of the tray (figure 1 objects 36 and 28). It would have been within the skill of one having ordinary skill in the art at the time the invention was made to have modified the Marsh et al. reference to include the ability to mount foil or a lip on the top of the tray in order to keep the trays contents free of dust.

19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include sterilized

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surgical instruments set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface (figure 2 objects 20 and 22) because this allows for the objects to be securely within the tray, and the contents of the tray to be free of dust.

20. For claims 7 and 8, the Howorth reference discloses the need for a working tray to put surgical instruments or other items place flat on the working surface (3-16). The reference discloses that the working tray could have any dimension (column 3, lines 20-24). The reference does not disclose the working surface being a rectangular tray with boundary walls higher than the instruments, the height of the boundary wall is slightly greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same, and the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air.

21. The Marsh et al. reference discloses a tray with boundary walls that would be higher than the surgical instruments (figure 1 objects 28 and 36 and column 3, lines 31-43). The reference does not disclose the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. The reference does not explicitly

state the boundary wall being rectangular. The reference does not disclose the boundary wall in the shape of a rectangle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the boundary wall in the shape of a rectangle since the examiner takes Official Notice of the equivalence of the tray/boundary wall in the shape of a circle of Marsh (objects 36 and 28) and the applicants tray/boundary wall in the shape of a rectangle for their use in the air tray and outlet art and the selection of any of these known equivalents to provide an tray for surgical items and an outlet for filtered air would be within the level of ordinary skill in the art.

22. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth et al. reference to include the working surface being a rectangular tray with boundary walls higher than the instruments, the height of the boundary wall is slightly greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same, and the height of the boundary wall is on the order of 200 to 300mm while maintaining the blanket of sterile air (figure 1 objects 28 and 36 and column 3, lines 31-43) because this allows for the objects to be securely within the tray and provided with a continuous flow of contaminant free airflow.

23. For claim 9, the Howorth reference does not disclose the rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second.

24. The Marsh et al. reference discloses the rate of flow of air from the outlets of the boundary wall (column 2, lines 30-32) is adjustable. The reference does not explicitly state is of the flow rate of air in the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second. It would be obvious to one having ordinary skill in the art at the time the invention was made that the speed at which the air exits is merely a design choice and is within the abilities of the Marsh et al. reference.

Furthermore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the flow rate of air in the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233

25. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the rate of flow of air from the outlets is of the order of 0.4 to 0.5 meters per second, and no less than approximately 0.35 meters per second (Marsh et al. column 2, lines 30-32) because this provides laminar air flow.

26. For claim 10 the Howorth et al. reference discloses the work tray being densely perforated with many substantially uniform distributed apertures to provide a substantially uniform flow of air through the work tray (figure 2 objects 22 a, b and 15). The reference does not disclose the work tray comprising boundary walls which are densely perforated to provide substantially uniform air through the work tray.

27. The Marsh et al. reference discloses the work tray comprising boundary walls which are densely perforated to provide substantially uniform air through the work tray (figure 1 object 36 and column 2, lines 24-37).

28. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work tray comprising boundary walls which are densely perforated to provide substantially uniform air through the work tray (Marsh et al. figure 1 object 36 and column 2, lines 24-37) because this allows for the objects to be securely within the tray and a supply of substantially contaminant free air flowing over the tray.

29. For claim 11, the Howorth reference does not explicitly state the construction of the part of the boundary wall comprising the outlets is such as to provide a pressure drop of the order of at least 10 Pascal's. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the construction of the part of the boundary wall comprising the outlets is such as to provide a pressure drop of the order of at least 10 Pascal's, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

30. For claim 12, the Howorth reference discloses a sterile air trolley having a sterile air cabinet comprising a casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets,

the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), and means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface, said means comprising, the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), and the filtered air is emitted inwardly over the work surface from the side walls in use (column 2, lines 24-28, "create an air barrier over the well" shows the filter emitting air inwardly also see figure 1 object 36). The reference does not disclose an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface, and the boundary wall comprising first an second pairs of opposing straight, parallel side walls. Merely changing the shape of the filter (from a circle, to the boundary wall comprising first an second pairs of opposing straight, parallel side walls) does not render patentability. The specification contains no disclosure of either the critical nature of this requirement or any unexpected results arising therefrom, and as such this requirement would be arbitrary and therefore obvious. Applicant must show that this requirement is critical. In re Woodruff, 16 USPQ 2d 1934.

31. The Marsh et al. reference discloses an upstanding boundary wall extending fully around the perimeter of the work surface whereby the work surface and boundary wall form a tray, the boundary wall extending fully around the perimeter of the work surface,

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and the walls emitting filtered air on all sides (figure 1, objects 36 and 28). The reference does not explicitly state the boundary wall being hollow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall being hollow since the examiner takes Official Notice of the equivalence of the wall of Marsh (objects 36 and 28) and the applicant's hollow wall for their use in the air outlet art and the selection of any of these known equivalents to provide an outlet for filtered air would be within the level of ordinary skill in the art.

32. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include an upstanding boundary wall extending fully around the perimeter of the work surface and boundary wall forming a tray, the boundary wall extending fully around the perimeter of the work surface and the walls emitting filtered air on all sides (Marsh et al. figure 4, figure 1, objects 36 and 28) because this allows for the objects to be sterilized to be securely within the apparatus and the all over flow of sterilized air. It would be obvious to one having ordinary skill in the art at the time the invention was made that the wall of Marsh (objects 36 and 28)

33. For claim 14, the Howorth reference discloses a sterile air trolley comprising a mobile casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and

column 2, lines 46-49), and means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface, said means comprising, the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects 22 a and b), and the filtered air is emitted inwardly over the work surface from the side walls in use (column 2, lines 24-28, "create an air barrier over the well" shows the filter emitting air inwardly also see figure 1 object 36). The reference does not disclose an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface, the air outlets facing only substantially inwardly towards the work surface from the boundary wall, and the boundary wall comprising first an second pairs of opposing straight, parallel side walls. Merely changing the shape of the filter (from a circle, to the boundary wall comprising first an second pairs of opposing straight, parallel side walls) does not render patentability. The specification contains no disclosure of either the critical nature of this requirement or any unexpected results arising therefrom, and as such this requirement would be arbitrary and therefore obvious. Applicant must show that this requirement is critical. In re Woodruff, 16 USPQ 2d 1934.

34. The Marsh et al. reference discloses an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and boundary wall form a tray, the boundary wall extending fully around the perimeter of the work surface, the walls emitting filtered air on all sides, and the air outlets facing only substantially

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inwardly towards the work surface from the boundary wall (figure 1, objects 36 and 28 column 2, lines 24-27). The reference does not explicitly state the boundary wall being hollow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall being hollow since the examiner takes Official Notice of the equivalence of the wall of Marsh (objects 36 and 28) and the applicants hollow wall for their use in the air outlet art and the selection of any of these known equivalents to provide an outlet for filtered air would be within the level of ordinary skill in the art.

35. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include an upstanding boundary wall extending around the perimeter of the work surface, whereby the work surface and boundary wall forming a tray, the boundary wall extending fully around the perimeter of the work surface, the walls emitting filtered air on all sides and the air outlets facing only substantially inwardly towards the work surface from the boundary wall (Marsh et al. figure 4, figure 1, objects 36 and 28, and column 2, lines 24-27) because this allows for the objects to be sterilized to be securely within the apparatus and the all over flow of sterilized air.

36. For claim 15, the Howorth reference discloses the need for all over flow of sterilized air from the work surface, and forming a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume (figure 2 objects 22 a and 22b). The reference does not disclose the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously

replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall.

37. The Marsh et al. reference discloses the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall (figure 1 objects 28 and 36, column 2, lines 24-37 and abstract).

38. It would be obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising layer of filtered air over the work surface within the sterile zone / volume defined by the boundary wall (Marsh et al. figure 1 objects 28 and 36, column 2, lines 24-37 and abstract) because this allows for the objects to be sterilized to be securely within the apparatus and the sterilized air to be distributed over the entire surface of the apparatus.

39. For claim 16, the Howorth reference discloses filtered air being emitted from the work tray on all sides (figure 2 objects 22 a and b). The reference does not disclose the all sides being in the shape of a tray that is rectangular, and with the boundary wall defining the four sides of the rectangle.

40. The Marsh et al. reference discloses the boundary wall defines all sides of the tray and the filtered air being emitted inwardly over the work surface from all sides (figure 4 object 36). The reference does not disclose the boundary wall in the shape of a

rectangle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the boundary wall in the shape of a rectangle since the examiner takes Official Notice of the equivalence of the tray/boundary wall in the shape of a circle of Marsh (objects 36 and 28) and the applicants tray/boundary wall in the shape of a rectangle for their use in the air tray and outlet art and the selection of any of these known equivalents to provide an tray for surgical items and an outlet for filtered air would be within the level of ordinary skill in the art.

41. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include all sides being in the shape of a tray that is rectangular, the boundary wall defining the four sides of the rectangle, and the filtered air being emitted inwardly over the work surface from all sides (Marsh et al. figure 4 object 36) because this allows for the objects to be sterilized to be securely within the working tray.

42. For claim 17, the Howorth reference discloses the trolley casing is in a modular form having a base unit housing the impeller and an upper unit comprising the work surface (figures 1 objects 11 and 12, and figure 2 object 17). The reference does not disclose the work surface being tray-shaped with a boundary wall, and the upper unit being readily demountable from and re-mountable to the base unit.

43. The Marsh et al. reference discloses the work surface being tray-shaped with a boundary wall (figure 1 objects 28 and 36).

44. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the work surface

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being tray-shaped with a boundary wall (Marsh et al. figure 1 objects 28 and 36)

because this allows for the objects to be securely within the working tray.

45. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the upper unit being readily demountable from and re-mountable to the base unit, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

46. For claim 18, the Howorth reference does not disclose sterilized surgical instruments are set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface.

47. The Marsh et al. reference discloses a tray that has the ability to have sterilized surgical instruments on the top of the surface, and to mount foil or a lid on the top of the tray (figure 1 objects 36 and 28). It would have been within the skill of one having ordinary skill in the art at the time the invention was made to have modified the Marsh et al. reference to include the ability to mount foil or a lip on the top of the tray in order to keep the trays contents free of dust.

48. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include sterilized surgical instruments set out on the work surface of the upper unit and sealed in by a film, foil or lid of barrier material that is mounted above the work surface (figure 2 objects 20 and 22) because this allows for the objects to be securely within the tray, and the contents of the tray to be free of dust.

49. For claim 19, the Howorth reference discloses the need for a working tray to put surgical instruments or other items place flat on the working surface (3-16). The reference discloses that the working tray could have any dimension (column 3, lines 20-24). The reference does not disclose the working surface being a rectangular tray with boundary walls higher than the instruments, the height of the boundary wall is slightly greater than the height of the any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same.

50. The Marsh et al. reference discloses a tray with boundary walls that would be higher than the surgical instruments (figure 1 objects 28 and 36 and column 3, lines 31-43). The reference does not explicitly state the boundary wall being rectangular. The reference does not disclose the boundary wall in the shape of a rectangle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the boundary wall in the shape of a rectangle since the examiner takes Official Notice of the equivalence of the tray/boundary wall in the shape of a circle of Marsh (objects 36 and 28) and the applicants tray/boundary wall in the shape of a rectangle for their use in the air tray and outlet art and the selection of any of these known equivalents to provide an tray for surgical items and an outlet for filtered air would be within the level of ordinary skill in the art.

51. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth et al. reference to include the working surface being a rectangular tray with boundary walls higher than the instruments, and the height of the boundary wall is slightly greater than the height of the

any of the instruments or other items placed flat on the work surface of the tray in order to fully enshroud the same (Marsh et al. figure 1 objects 28 and 36 and column 3, lines 31-43) because this allows for the objects to be securely within the tray and provided with a continuous flow of contaminant free airflow.

52. For claims 20 and 21, the Howorth et al. reference does not disclose air outlets not being directed upwardly or outwardly.

53. The Marsh et al. reference discloses no air outlets being directed upwardly or outwardly (figure 4 object 36 and column 2, lines 24-37).

54. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth et al. reference to include no air outlets being directed upwardly or outwardly (Marsh et al. figure 4 object 36 and column 2, lines 24-37) because this provides a continuous flow of contaminant free air over the enclosed area.

55. For claims 22 and 23, the Howorth et al. reference does not disclose the upstanding boundary wall does not have an inwardly projecting lip and the boundary walls is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall.

56. The Marsh et al. reference discloses the boundary walls is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall (columns 2, lines 24-37 and 56-69) and the upstanding boundary wall does have an inwardly projecting lip in order to give direction to the air flow (column 2, lines 38-42).

57. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include the boundary walls is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall (Marsh et al. columns 2, lines 24-37 and 56-69) to provide and air barrier against external contamination and to have the upstanding boundary wall not having an inwardly projecting lip (Marsh et al. column 2, lines 38-42) in order to allow for the expansion of the air.

Response to Arguments

Applicant's arguments filed 04/20/2010 have been fully considered but they are not persuasive.

For claim 1, 12 and 14, the Applicant contends "As the air flow from all four sides merge, it rises as a column. This is the continuously replenished rising layer of filtered air described in the independent claims. It provides a sterile air zone for surgical implements placed on the work surface. The robust blanket or layer of air described in the patent is clearly different from the turbulent vortex described in the Marsh '999."

The examiner disagrees. The Marsh reference discloses "The diffuser expands under the influence of the air-flow directed there through and discharges a uniform mass of air (can be interpreted as a layer) in a 360° arc towards the center of the diffuser well. As the rushing masses of air collide, they form a vertically rising vortex which provides an air barrier against external contamination". As can be seen on page

6, lines 33-34 of the applicant's specification, this is exactly the flow that the applicant describes e.g. "The air flows in from all four sides and rises as a column as the air flows merge." The applicant fails to show how this column is different from that of the Marsh reference's vortex.

The applicant argues "The Examiner is also reminded that a means-plus-function claim element requires examination pursuant to 35 U.S.C. § 112, 6th paragraph and MPEP 2181. This requires a two-step process. First, to find a means-plus-function claim limitation in a prior art reference, the asserted prior art must include the means or step for performing the function specified in the claim. Second, the asserted prior art must also include the structure from Applicant's specification (or equivalent structure) for implementing the claimed function. MPEP 2181, see also *In re Donaldson Company*, 16 F3d 1189, 1193 (Fed. Cir. 1994), and *Fresenius USA, Inc. v. Baxter International, Inc.*, 582 F3d 1288, 1299 (Fed. Cir. 2009). With respect to the means-plus-function claim element in the amended independent claims, the applied prior art fails on both accounts. The applied art does not identify either the recited function or any structure that could implement the recited function. "

The examiner disagrees. The applicant has failed to meet the requirements to invoke 35 U.S.C. § 112, 6th paragraph. See the MPEP 2181 "Identifying a 35 U.S.C. § 112, 6th paragraph Limitation".

"A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets

the following 3-prong analysis:

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- (A) the claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language;
and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function."

Claims 1, 12 and 14 all include the "means for" phrase being modified by sufficient structure for achieving the specified function. Therefore the applicant's arguments are moot. Furthermore as can be seen in the rejection above, the combination of the Howorth and Marsh references disclose the "means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface." The applicant argues "Howorth '956 patent does not contain at least the following claim limitations: 1) means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface; 2) an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and the boundary wall form a tray; 3) the boundary wall being hollow and extending fully around the perimeter of the work surface; 4) directing filtered air into the boundary wall and emitting the filtered air through outlets in the boundary wall facing inwardly of the boundary wall over the work surface from opposing sides; and 5) a boundary wall comprising first and second pairs of opposing straight parallel sidewalls such that filtered air is emitted inwardly over the work surface from opposing straight parallel sidewalls in use." and "Marsh '999 patent does not contain at least the following claimed

limitations: 1) means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface; 2) a hollow boundary wall extending fully around the perimeter of the work surface; 3) a hollow boundary wall comprising first and second pairs of opposing straight parallel sidewalls; and 4) directing filtered air into the hollow boundary wall and emitting the filtered air through outlets in the boundary wall facing inwardly of the boundary wall over the work surface from opposing straight parallel sides."

58. The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For claim 1, the Howorth reference discloses a sterile air trolley comprising a mobile casing having at least one air inlet in its lower region (figure 1 objects 11, 13 and 14) and a plurality of air outlets in its upper region (figure 1, object 22a, and b) and enclosing an impeller operative to move air in through the at least one inlet (column 1, lines 33-34), through a filter and out of the casing by way of the outlets, the upper region of the casing providing a substantially horizontal work surface (figure 1, objects 15, and column 2, lines 46-49), and means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface, said means comprising, the work surface consisting essentially of air outlets, the filtered air entering the hollow work surface, and exiting the air outlets which are all over the working tray (figure 2 objects

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22 a and b), and the filtered air is emitted inwardly over the work surface from the side walls in use (column 2, lines 24-28, "create an air barrier over the well" shows the filter emitting air inwardly also see figure 1 object 36). The reference does not disclose an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall form a tray, the boundary wall being hollow and extending fully around the perimeter of the work surface, and the boundary wall comprising first an second pairs of opposing straight, parallel side walls. Merely changing the shape of the filter (from a circle, to the boundary wall comprising first an second pairs of opposing straight, parallel side walls) does not render patentability. The specification contains no disclosure of either the critical nature of this requirement or any unexpected results arising therefrom, and as such this requirement would be arbitrary and therefore obvious. Applicant must show that this requirement is critical. In re Woodruff, 16 USPQ 2d 1934.

59. The Marsh et al. reference discloses an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall form a tray, the boundary wall extending fully around the perimeter of the work surface, and the walls emitting filtered air on all sides (figure 1, objects 36 and 28). The reference does not explicitly state the boundary wall being hollow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall being hollow since the examiner takes Official Notice of the equivalence of the wall of Marsh (objects 36 and 28) and the applicants hollow wall for their use in the air outlet art and

the selection of any of these known equivalents to provide an outlet for filtered air would be within the level of ordinary skill in the art.

60. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Howorth reference to include an upstanding boundary wall extending around the perimeter whereby the work surface and boundary wall forming a tray, the boundary wall extending fully around the perimeter of the work surface and the walls emitting filtered air on all sides (Marsh et al. figure 4, figure 1, objects 36 and 28) because this allows for the objects to be sterilized to be securely within the apparatus and the all over flow of sterilized air.

61. The applicant also argues "Marsh et al., at Col. 1, lines 19-24, make clear that their invention is not a laminar flow workbench."

62. The examiner agrees. The applicant is not claiming a **laminar** flow work bench. No where within the specification does the applicant disclose laminar flow. Merely stating that there is a robust blanket of air does not equate to laminar flow. "Blanket" does not translate to the type of air flow, or the directionality. The examiner interprets "blanket" to be a body of air over the work surface.

63. The applicant argues "Nowhere does Marsh suggest that the "diffuser" could consist merely of a hollow wall having air outlets facing inwardly over the work surface. Of course such a structure would frustrate the purpose of the "diffuser" in Marsh which is to diffuse the air flow. Neither Marsh, nor Howorth, discloses or suggests a hollow wall having air outlets facing inwardly over the work surface."

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64. The examiner disagrees. As disclosed in the rejection above, the Howorth reference discloses the hollow wall having air outlets, and the Marsh reference discloses air outlets facing inwardly over the work surface. The purpose of the "diffuser" in the Marsh reference is to discharge a uniform mass of air in order to provide an air barrier against external contamination (column 2, lines 63-68).

65. The applicant contends "it is legally improper to infer that Marsh somehow suggests a rectangular, hollow boundary wall. The diffuser in Marsh is annular so that it creates a rising vortex. The claimed structure on the other hand requires that the hollow boundary wall comprise first and second pairs of opposing straight parallel sidewalls. The claimed structure does not create a rising vortex."

66. The examiner disagrees. The purpose of the Marsh reference is to create a uniform mass of air which is entering the workspace from all sides (360°) and therefore provide an air barrier against external contamination (column 2, lines 63-68). Merely changing the shape of the work space to be a rectangle would still allow the air to enter as a uniform mass from all sides (360°). Furthermore the claimed structure does not specifically teach away from creating a rising vortex. The specification describes "The air flows in from all four sides and rises as a column as the air flows merge." (page 6, lines 33-34). This definition of the air flow within the applicant's specification appears to be teaching creating a rising vortex.

67. For claim 5, the applicant contends "It would not have been obvious from Marsh that by providing an upper unit comprising a boundary wall and work surface wherein the upper unit is demountable from a base unit, this would be advantageous for

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sterilizing the work surface and surgical instruments together. The upper unit of the present invention can be sterilized in an autoclave; autoclaves typically sterilize equipment by subjecting them to high pressure steam at 121°C or more. It is known that polyurethane foam has a poor response to steam sterilization from autoclaves, and polyurethane foam is likely to be damaged by the high temperature steam in an autoclave. Therefore, even if a person of ordinary skill were to provide the trolley of Howorth with an upper unit having a work surface and a diffuser like that of Marsh, they would not be motivated to make the upper unit demountable for sterilization as the reticulated polyurethane foam of the diffuser of Marsh would not be properly sterilized by an autoclave, and may suffer damage from the high temperature steam in an autoclave."

68. The examiner disagrees. It is well known in the art to have a tray which is known to carry objects, to be mobile (e.g. demountable from a base unit) in order to transfer said objects. Furthermore the applicant is arguing unexpected results (e.g. being able to be properly sterilized by an autoclave) without providing any evidence of such within the specification or within the arguments, therefore rendering the applicants arguments moot. Lastly there is no mention of said autoclave within the applicant's specification also rendering the applicant's arguments moot.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER ORLANDO whose telephone number is (571)270-3149. The examiner can normally be reached on Mon.-Thurs. (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AO

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797